Presentation 16 – Timothy O'Leary

VA Tissue Banking

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Types of Tissue Bank

- Biopsy/autopsy specimens
  - May be frozen or paraffin-embedded
  - Quality depends upon many technical factors
- Serum or blood
- Urine
- Extracted nucleic acids

What is a Tissue Bank?

- Specimens collected and stored for future research purposes that are not specified in the original research protocol are considered "banked specimens."
- Specimens that are collected and retained for diagnostic purposes are not considered "banked specimens" until research use is contemplated.

Examples of VA Tissue Banks

- Bronx VA – brain
- Denver VA – lung cancer
- Iowa city VA – blood for hepatitis C studies
- San Francisco – blood for genetic studies of heart disease and mental health
- Palo Alto –CNS tissues
- West LA – postmortem CNS

How many VA Tissue Banks Are There?

- As of July, 2002 we believe that 53 stations banked tissue, with 18 banking tissue off-site.
- Details are available on only 37 of these sites.

Starting a New Repository

- Demonstrate unmet demand and scientific purpose.
- Meet technical and ethical standards.
- Demonstrate that the cost of operation is appropriate and that it serves a VA purpose.

Non-VA Tissue Banks

- May deposit in NCI Cooperative Oncology Group or NIDA center for Genetics Studies tissue banks without waiver.
- Waiver requires justification:
  - Benefit to veterans
  - Link to clinical data only at VA
  - VA IRB and research committee approval
  - Protocol
  - Informed consent document

Sending Research Specimens Outside VA

- If specimens are sent to a non-VA institution for analysis, such analysis should be outlined in the original research protocol.
- A written agreement must specify the analysis/test to be performed outside the VA.
- The remainder of the specimens must be returned to the original VA for destruction. Alternatively, specimens and related biomaterials may be destroyed at the non-VA institution on condition that the institution certifies, in writing, that the specimens have been destroyed.
- Remaining specimens and/or related biomaterials may not be retained and/or stored by the non-VA institution.

Clinical Data Considerations

- Clinical and personal data must be maintained under VA control. The clinical information that is shared should not contain any unique identifiers that can be linked to a human subject.
- It is imperative that human research subjects donating biological specimens receive the highest level of protection with regard to their linked clinical and personal data.

Informed Consent Must Specify

- If specimen will be used for future research and must provide a choice for the type of research (research specified in the consent form; research conducted by the PI only; research conducted by other investigators; research related to specific diseases; gene testing; etc.).
- If the specimen will be stored without any identifier or if the subject's identifier and clinical data are linked to the specimen.
- If the human subject will be contacted after the completion of the original study.
- If the specimens and all links to clinical data are destroyed or removed from the bank upon the subject's request.
- The disposition of the specimen after completion of the study or at the end of the banking period.
- Any potential conflict of interest or financial gains for the investigators or the participating institution.

Communication of Research Results to Clinicians and Human Subjects

- The Clinical Laboratory Improvement Act of 1988 prohibits communication of patient-specific research laboratory results to either subjects or clinicians.
- The general research findings should be available to both clinicians and human subjects.

Other Resources

- NINDS-sponsored brain banks in Parkinson Disease, epilepsy and stroke.

MAVERICK Query

- "Does the current supply of brain tisssue meet the demand by VAHCS research?"
- "Evidently, there are few requests to existing VAHCS brain banks by VAHCS research."
- *Most requests come from outside VA.*

Starting a New Bank

- What is the scientific need?
- What are the technical requirements?
- Are the specimens available?
- What is the cost of obtaining the specimens?
- How will specimens be distributed?
- What are the policy requirements?
- How will tissue bank show worth?
- How will policies protect veterans' interests?

Conclusions

- VA Tissue Banks support the care of future veterans by facilitating research by today's veterans.
- Must demonstrate that they are needed for high-quality hypothesis-driven research.
- Must respect the right of veterans for privacy and autonomy.
- Must not unnecessarily duplicate efforts of other federal agencies.